IN THE UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TEXAS Beaumont Division

Cyd Marie Badon

Plaintiff,

Plaintiff,

SCOMPLAINT FOR PERSONAL INJURIES AND DAMAGES

vs.

Alphatec Spine a/k/a Alphatec
Supply Company

Defendants.

NATURE OF THE CASE

1. Plaintiff, Cyd Marie Badon, developed severe back pain caused by the fracture of orthopedic bone screws used in her lower back. This lawsuit asserts claims for negligence, strict product liability for design defect, strict product liability for manufacturing defect against Alphatec Spine a/k/a Alphatec Supply Company who was responsible for the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of the defective screws.

JURISDICTION AND VENUE

- 2. This court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §1332 (diversity of citizenship). The matter in controversy in this civil action exceeds the sum or value of \$75,000, exclusive of costs and interests, as to each defendant, and is between citizens of different states.
- 3. Venue in this District is proper under 28 U.S.C. §1391. The events and omissions giving rise to this cause of action occurred in substantial part in this District, where defendants transact business.

THE PARTIES

Plaintiff

4. At all relevant times plaintiff was a resident and citizen of Orange County, Texas.

Defendant

5. Defendant Alphatec Spine a/k/a Alphatec Supply Company is a California corporation with its principal place of business in Carlsbad, California. At all relevant times, this defendant was engaged in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including Zodiac polyaxial screws.

FACTUAL ALLEGATIONS

Plaintiff's Injuries

- 6. Plaintiff Cyd Marie Badon had orthopedic bone screws placed as part of a spinal surgery completed on January 18, 2006.
- 7. In approximately October of 2007 x-rays of Ms. Badon's back indicated that one of the screws had broken.
- 8. Ms. Badon had some back pain between October of 2007 and November of 2009, but it was her understanding and reasonable belief, based on her conversations with her doctors, that the manageable back pain she experienced between October of 2007 and November of 2009 was the type of pain to be expected from a two level lumbar fusion. There was no indication that the screw fracture had resulted in any increased injury or pain, but rather was an incidental finding.
- 9. In November of 2009, Ms. Badon fell and subsequently began having severe back pain.
 - 10. An MRI performed on February 18, 2010 showed a second fractured screw.

- 11. Ms. Badon's pain increased dramatically following and as a result of the fracture of the second screw.
- 12. Ms. Badon's increased pain and disability associated with the fracture of the second screw necessitated a surgery to remove and replace the defective screws.
- 13. As a result of the failure of the Zodiac polyaxial screws, Plaintiff has the following damages: medical expenses, past and future; lost earnings and earning capacity, past and future; physical impairment, past and future; disfigurement, past and future; financial losses, past and future; pain and suffering, past and future; as well as mental anguish, past and future.

Defendants' Misconduct

- 14. At all material times, Defendant was responsible for designing, manufacturing, producing, testing, studying, inspecting, labeling, marketing, advertising, selling, promoting, and/or distributing the defective screws.
- 15. Defendant had an obligation to know, analyze, and disclose scientific and medical information about its orthopedic screws. Defendant failed to do so by failing to disclose defects in the manufacturing and design of the orthopedic screws in question, 40mm x 6.5mm Zodiac polyaxial screws.
- 16. Defendant made claims regarding the benefits of the Zodiac polyaxial screws that Defendant knew or should have known were false and misleading. Defendant failed to adequately disclose the true health consequences, and the true risks of failure associated with those screws.
- 17. Defendant failed to conduct adequate pre-marketing clinical testing and research, and failed to conduct adequate post-marketing surveillance, to determine the safety of the Zodiac polyaxial screws.
 - 18. Defendant failed to disclose on their warning labels or elsewhere that adequate

pre-marketing clinical testing and research, and adequate post-marketing surveillance, had not been done, thereby giving the false impression that the Zodiac polyaxial screws had been sufficiently tested.

- 19. Plaintiff would not have agreed to the implantation of Zodiac polyaxial screws had Defendants disclosed the true health consequences, risks, and adverse events associated with the defective design and manufacture of those screws.
- 20. Defendant's nondisclosures and misrepresentations as alleged herein were material, and were substantial factors that contributed directly and causally, and naturally and necessarily, to the serious injuries and damages that plaintiff has suffered.

CLAIMS FOR RELIEF

Negligence

- 21. Plaintiff realleges all previous paragraphs.
- 22. Defendants introduced the Zodiac polyaxial screws described herein into the stream of commerce.
- 23. At all material times, Defendant had a duty to Plaintiff and other users of Zodiac polyaxial screws to exercise reasonable care in order to properly design, manufacture, produce, test, study, inspect, label, market, advertise, sell, promote, and distribute those screws. This includes a duty to adequately warn about defects, risks and dangers associated with Zodiac polyaxial screws.
- 24. Defendant knew, or in the exercise of reasonable care should have known, that the Zodiac polyaxial screws were of such a nature that they were not properly designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted, and distributed, and they were likely to cause injury to those in whom they were implanted.

- 25. Defendant was negligent in the design, manufacture, production, testing, study, inspection, labeling, marketing, advertising, sales, promotion, and distribution of their Zodiac polyaxial screws and breached duties they owed as set forth herein. In particular, defendants:
 - Failed to use due care in the manufacture of their Zodiac polyaxial screws to prevent the aforementioned risks;
 - b. Failed to use due care in the design of their Zodiac polyaxial screws to prevent the aforementioned risks;
 - c. Failed to conduct adequate pre-clinical testing and research to determine the safety of their Zodiac polyaxial screws;
 - d. Failed to conduct adequate post-marketing surveillance to determine the safety of their Zodiac polyaxial screws;
 - e. Failed to accompany their products with proper warnings regarding all possible adverse effects associated with the use of their Zodiac polyaxial screws and the comparative severity and duration of such adverse effects;
 - f. Failed to use due care in the development of their Zodiac polyaxial screws to prevent the aforementioned risks;
 - g. Failed to use due care in the manufacture of their Zodiac polyaxial screws to prevent the aforementioned risks to individuals;
 - h. Failed to use due care in the inspection of their Zodiac polyaxial screws to prevent the aforementioned risks to individuals;
 - Failed to use due care in the labeling of their Zodiac polyaxial screws to prevent the aforementioned risks to individuals;
 - Failed to use due care in the marketing of their Zodiac polyaxial screws to prevent the aforementioned risks to individuals;

- k. Failed to use due care in the promotion of their Zodiac polyaxial screws to prevent the aforementioned risks to individuals;
- Failed to use due care in the selling of their Zodiac polyaxial screws to prevent the aforementioned risks to individuals;
- m. Failed to provide adequate information to healthcare providers for the appropriate use of their Zodiac polyaxial screws;
- n. Failed to adequately warn about the health consequences, risks, and adverse events caused by their Zodiac polyaxial screws; and
- o. Were otherwise careless and negligent.
- 26. Defendant knew or should have known that their Zodiac polyaxial screws caused unreasonable harm that many users would be unable to remedy by any means. Despite this, Defendant continued to promote and market their Zodiac polyaxial screws for use by consumers, including Plaintiff.
- 27. It was foreseeable to Defendants that consumers, including Plaintiff, would suffer injury as a result of Defendant's failure to exercise ordinary care as described herein.
- 28. As a direct and proximate result of Defendant's conduct, plaintiff suffered the injuries and damages specified herein.

Strict Liability: Manufacturing Defect

- 29. Plaintiff realleges all previous paragraphs.
- 30. Defendant manufactured and/or supplied the Zodiac polyaxial screws described herein, and at all material times were in the business of doing so. They placed those screws into the stream of commerce. Those screws were expected to and did reach Plaintiff without substantial change in their condition.
 - 31. When Defendant placed the Zodiac polyaxial screws that were ultimately

implanted in Ms. Badon into the stream of commerce, those screws were defectively manufactured and unreasonably dangerous as those terms are defined by Texas law.

- 32. At time the Zodiac polyaxial screws implanted in Ms. Badon left Defendant's hands, they were in a condition not contemplated by Plaintiff.
- 33. The Zodiac polyaxial screws implanted in Ms. Badon were dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased them. They were more dangerous than Plaintiff contemplated.
- 34. The risks of the Zodiac polyaxial screws implanted in Ms. Badon outweighed their utility.
- 35. The manufacturing defects in the Zodiac polyaxial screws implanted in Ms. Badon were the producing cause of the injuries and damages specified herein.

Strict Liability: Design Defect

- 36. Plaintiff realleges all previous paragraphs.
- 37. Defendant manufactured and/or supplied the Zodiac polyaxial screws described herein, and at all material times were in the business of doing so. They placed those screws into the stream of commerce. The screws were expected to, and did, reach Plaintiff without substantial change in their condition.
- 38. When Defendant placed the Zodiac polyaxial screws that were ultimately implanted in Ms. Badon into the stream of commerce, those screws were defectively designed and unreasonably dangerous as those terms are defined by Texas law.
- 39. The Zodiac polyaxial screws were each dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased them. They were more dangerous than Plaintiff contemplated.
 - 40. The risks of the Zodiac polyaxial screws outweigh their utility.

- 41. At the time of manufacture, the likelihood the product would cause the Plaintiff's harm or similar harms, and the seriousness of those harms, outweighed Defendants' burden in designing a product that would have prevented those harms.
- 42. There were practicable and technologically and economically feasible safer alternatives to the Zodiac polyaxial screws for implantation in the low back.
- 43. The defect in the product was a producing cause of the injuries and damages specified herein.

PRAYER FOR RELIEF

WHEREFORE, plaintiff seeks judgment in her favor against the defendants, jointly and severally, as follows:

- 1. Economic and non-economic damages for: medical expenses, past and future; lost earnings and earning capacity, past and future; physical impairment, past and future; disfigurement, past and future; financial losses, past and future; pain and suffering, past and future; as well as mental anguish, past and future in an amount in excess of \$75,000 as provided by law and to be supported by the evidence at trial;
 - 2. An award of costs of suit as well as interest, as provided by law;
 - 3. Such other legal and equitable relief as this Court deems just and proper.

JURY DEMAND

Plaintiff requests a trial by jury.

Signed on this 1st day of November, 2011.

Respectfully submitted,

By: /s/ Christopher T. Kirchmer

PROVOST ★ UMPHREY LAW FIRM, L.L.P.

Christopher T. Kirchmer Texas Bar No. 00794099 490 Park Street P. O. Box 4905 Beaumont, Texas 77704 (409) 835-6000 telephone (409) 813-8612 facsimile Ckirchmer@pulf.com - email